**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Applicant: | Mohan Krishnan et al. | Examiner: Joseph Stoklosa |
| Serial No.: | 10/731,421 | Group Art Unit: 3762 |
| Filed: | December 9, 2003 | Docket: 279.650US1 |
| Title: | ENDOCARDIAL LEAD FOR A LEFT HEART CHAMBER | |

## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

The applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated below:

*§103 Rejection of the Claims*

Claims 1, 5, 7 and 9-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Helland et al. (U.S. Patent No. 5,318,572).

Applicant maintains the position in the response submitted August 13, 2008 that claims 1, 5, 7 and 9-18 are not obvious in view of the cited reference since there is no suggestion or motivation to modify the reference. Applicant believes the Examiner's position is a clear error of fact regarding the characterization of the reference.

*Claims 1, 5, 7, 9, and 10*

Applicant believes claim 1 is not obvious in view of the Helland reference since the reference does not include or suggest each limitation recited in the claim. For instance, Applicant cannot find in the Helland reference: wherein the outer surface of the lead body is adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream, as recited in claim 1. In contrast, Helland does not describe anything about the lead body outer surface. Col. 4, lines 8-10 of Helland merely disclose that the lead is formed of a biocompatible, biostable material. However, nothing in the Helland reference indicates or suggests that the lead body is adapted such that a layer of blood cells is formed on the outer

surface when exposed to a bloodstream, as recited in claim 1.

In the Advisory Action, the Examiner asserts that in light of Helland disclosing that the lead body is biocompatible and biostable that "the system of Helland will also be able to form such a layer of blood cells upon implantation and exposure to the bloodstream, as such function is an expected biological reaction to an implanted foreign body." (Page 2 of Advisory Action).

Applicant traverses this rationale. There is nothing in the Helland reference that explicitly or implicitly teaches such subject matter. The Examiner is apparently finding that the subject matter is inherent in the reference. Applicant respectfully disagrees because the Office Action has not established a prima facie case of inherency because, as recited in MPEP § 2112, "In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art," citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). In this case, the Office Action asserts that the reference lead will be able to form a layer of blood cells. Thus, the Office Action does not even assert that the allegedly inherent characteristic is necessary, let alone provide a basis in fact and/or technical reasoning.

Also, Applicant cannot find in Helland: wherein the outer surface of the ring electrode includes a textured coating including titanium microspheres, as recited in claim 1. Helland does not include or suggest a ring electrode having a textured coating.

The Final Office Action asserts that it would have been obvious "to modify the system as taught by Helland with a ring electrode since such a modification is well known in the medical art for providing the predicable results of providing bi-polar pacing with the tip electrode, pacing multiple sites, or with a ring electrode minimizing thrombosis by not having the ring electrode contacting the vessel wall." (Pages 2-3 of Final Office Action).

However, even if Helland used a ring electrode, there is nothing in the Helland reference to suggest that the ring electrode would be texturized. The Helland reference discusses that the texturizing treatment on the electrode distal tip 60 is to "create a plurality of pore sites and interstitial porosity for chronic ingrowth of tissue." (Col. 6, lines 6-8). Neither the Office Action nor Helland give any indication of a need for such chronic ingrowth of tissue on a ring electrode. Accordingly, there is no reason or suggestion for such a modification of the Helland

reference.

Claims 5, 7, 9, and 10 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

*Claims 11-16*

Applicant believes claim 11 is not obvious in view of the Helland reference since the reference does not include or suggest each limitation recited in the claim. For instance, Applicant cannot find in the reference: wherein the lead body has a textured outer surface adapted to form a layer of blood cells on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface, as recited in claim 11. As discussed above, Helland does not describe anything about the lead body outer surface. Col 4, lines 8-10 merely disclose that the lead is formed of a biocompatible material.

Moreover, Applicant cannot find in the Helland reference: wherein the ring electrode includes an outer textured surface including titanium microspheres, as recited in claim 11. As discussed above, neither the Office Action nor Helland give any indication of a need for such chronic ingrowth of tissue on a ring electrode. Accordingly, there is no reason or suggestion for such a modification of the Helland reference.

Claims 12-16 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

*Claims 17 and 18*

Applicant believes claim 17 is not obvious in view of the Helland reference since the reference does not include or suggest each limitation recited in the claim. For instance, Applicant cannot find in the Helland reference: forming the lead body such that a layer of blood cells is formed on an outer surface of the lead body when exposed to a bloodstream, as recited in claim 17. As discussed above, Helland does not describe anything about the lead body outer surface. Col 4, lines 8-10 merely disclose that the lead is formed of a biocompatible material.

Moreover, Applicant cannot find in the Helland reference: a titanium microsphere outer surface coating on at least a portion of the ring electrode, as recited in claim 17. As discussed above, neither the Office Action nor Helland give any indication of a need for such chronic ingrowth of tissue on a ring electrode. Accordingly, there is no reason or suggestion for such a

modification of the Helland reference.

Claim 18 includes each limitation of its parent claim and is therefore also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

## CONCLUSION

The applicant respectfully submits that all of the pending claims are in condition for allowance, and such action is earnestly solicited. The Examiner is invited to telephone the below-signed attorney at (612) 359-3267 to discuss any questions which may remain with respect to the present application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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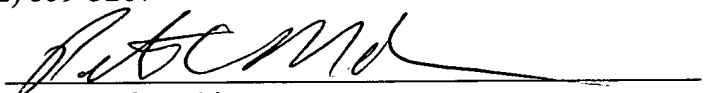
Date 9/15/08 By 

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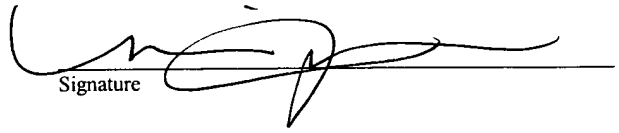
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